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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,664	05/02/2005	Andrzej Czernecki	POL0005-PCT	5014
36183 7590 12/26/2007 PAUL, HASTINGS, JANOFSKY & WALKER LLP 875 15th Street, NW Washington, DC 20005			EXAMINER TOWA, RENE T	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,664

Applicant(s)

CZERNECKI ET AL.

Examiner

Rene Towa

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4 and 8-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office is responsive to an amendment filed June 11, 2007. Claims 3-4 & 8-19 are pending. No claim has been amended. No new claim has been added. Claims 1-2 and 5-7 are cancelled.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 12 & 17-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutynowski et al. (US 6,613,064) in view of Simons et al. (US 5,871,494).

In regards to **claim 12**, Rutynowski et al. disclose a puncturing device for regulating force of puncture comprising:

a sleeve 1 having a first end and second end, and defining a sleeve axis;

a push element 2 located at the first end of the sleeve 1;

a piston 5 slidably mounted within the sleeve 1, the piston 5 having a wing 12 configured to rest on an edge of the sleeve 1 and prevent the piston 5 from sliding through the sleeve 1, and the piston 5 having a puncturing tip 8 on a side of the piston 5 opposite to the first end of the sleeve 1; and

a drive spring 10 within the sleeve 1 and compressed between the push element 2 and the piston 5, and

the drive spring 10 being compressed until the push element 2 presses the piston 5 sufficiently enough to break the wing 12, at which point the drive spring 10 expands and drives the piston 5 toward the second end of the sleeve 1 (see figs. 1-2 & 4; column 2/lines 1-7 & 11-22; see claim 3 of Rutynowski et al.).

In regards to **claim 17**, Rutynowski et al. disclose a device wherein the wing 12 configured to rest on an upper edge 13 of the sleeve 1 (see fig. 4).

In regards to **claim 18**, Rutynowski et al. disclose a device wherein the piston 5 having a second wing 12 configured to rest on an edge 13 of the sleeve 1 (see fig. 4).

In regards to **claim 19**, Rutynowski et al. disclose a device wherein the piston comprising a central body 5, a push rod 6 on a side of the central body proximate to the first end of the sleeve 1, and a fin 7 on a side of the central body proximate the second end of the sleeve 1, wherein the push element 2 presses on the push rod (see figs. 1-2 & 4).

Rutynowski et al. disclose a device, as described above, that teaches all the limitations of the claims except Rutynowski et al. do not disclose a force-adjusting member.

However, Simons et al. disclose a device 500 comprising a force-adjusting member (502, 528) turnably mounted on the device body 526; wherein the force adjusting member (502, 528) adjusts a distance within which the spring 532 is

compressed (see figs. 5A-B & 6A-F; column 4/lines 8-20; column 11/lines 39-52; column 12/lines 55-64).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. with a force-adjusting member similar to that of Simons et al. in order to customize the lancing force to provide an adequate blood sample and to minimize pain (see Simons et al., column 4/lines 8-11).

4. **Claims 3-4, 8-11 & 13-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutynowski et al. ('064) in view of Simons et al. ('494) further in view of Chelak et al. (US 6,558,402).

Rutynowski et al. as modified by Simons et al. discloses a device, as described above, that teaches all the limitations of the claim except Rutynowski et al. as modified by Simons et al. do not teach a force-adjusting member comprising an inwardly directed pair of oblique half-ring, or stair-shaped or gradient shaped member.

However, Chelak et al. disclose a device comprising a stair-shaped or gradient shaped member 106 (see fig. 3D).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of except Rutynowski et al. as modified by Simons et al. with a half ring, stair-shaped or gradient member similar to that of Chelak et al. since such a modification would amount to a design choice that serves the same purpose of varying the pre-load (i.e. perhaps by modifying the trigger system of Simons et al. to include a stair or gradient shaped

member instead). Moreover, it has previously been held that merely changing the shape (i.e. shape of the trigger) is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. as modified by Simons et al. and Chelak et al., above, with a force-adjusting member mounted at a proximal end thereof since such a modification would amount to a design choice. It has previously been held that merely shifting location of parts is not patentable--See *In re Japikse*, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).

Response to Arguments

5. Applicant's arguments filed June 11, 2007 have been fully considered but they are not persuasive. Applicant argues that the "force adjusting" of Simons is different from the force adjusting of the instant invention. This argument has been considered but has not been deemed persuasive.

In regards to the Applicant's argument that the "force adjusting" of Simons is different from the force adjusting of the instant invention, the Examiner respectfully traverses. First, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the force adjusting member of the instant invention changes the force with which the puncturing tip is propelled forward (see Remarks, at pages 8-9)) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, MPEP, section 2111.01 (III), also recites:

An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning) (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings"). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). See also *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) and MPEP § 2173.05(a). (Emphasis added).

As such, absent any special definition set forth in the specifications reasonable clarity, deliberateness, and precision, the terms "force adjusting member" and "adjustable push element" are hereby attributed a broad reasonable interpretation rather than a force adjusting member that changes the force with which the puncturing tip is propelled forward. In fact, Simons discloses a system wherein a force (i.e. whether preload or lancing force) is adjusted via compression of a spring through a "force-adjusting member," as such, the Examiner's rejection, as explained on page 4 of the last Office action, states that:

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. with a force-adjusting member similar to that of Simons et al. **in order to customize the lancing force** to provide an adequate blood sample and to minimize pain (see Simons et al., column 4/lines 8-11) [Emphasis added].

Applicant claims that the device of Simons only permits adjustment of both the puncture depth of the lancet and the preload force. However,

Column 1, lines 5-10 of Simons read as follows:

The present invention relates to techniques for obtaining and analyzing blood samples, and more particularly to techniques for lancing the skin with a controlled force obtaining and analyzing blood samples in a convenient manner [Emphasis added].

Column 4, lines 8-11 & 12-16 of Simons reads as follows:

In an embodiment of the blood sampling apparatus, the preload force is adjustable to allow the user to customize the lancing force to provide an adequate blood sample and to minimize pain [Emphasis added].

Therefore, using the apparatus of the present invention, the user can have significant control of the force and depth of lancing, thereby finding the ideal combination that enables him to collect adequate blood without undue amount of suffering [Emphasis added].

As such, it is indisputable that the device of Simons controls the force of lancing contrary to the Applicant's assertion.

As such, even though, Simons teaches a device that controls the lancing force by directly controlling the preload, the technique by which Simons does that renders Applicant's invention obvious since, similar to Simons, Applicant compresses a spring in order to adjust or control the desired force (i.e. whether preload or lancing force). Moreover, it appears that Applicant is not the first to discover this concept, newly discovered prior art, US 7,087,068 to Marshall et al. fully discloses a lancing device comprising a force adjusting member 39 that adjusts the distance over which its drive spring 38 is compressed so as to thereby adjust the lancing force.

In view of the foregoing, the rejection over Simons et al. are maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/RTT/

